

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SANOFI AVENTIS and) SANOFI AVENTIS U.S. LLC,) Plaintiffs,)) v.) WOCKHARDT LIMITED and) WOCKHARDT USA, INC.,) Defendants.) -----) WOCKHARDT LIMITED and) WOCKHARDT USA, INC.,) Counterclaim Plaintiffs,) v.) SANOFI AVENTIS and) SANOFI AVENTIS U.S. LLC,) Counterclaim Defendants.) -----)	C.A. No. 08-150-GMS
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**ANSWER AND COUNTERCLAIMS OF DEFENDANTS
WOCKHARDT LIMITED AND WOCKHARDT USA, INC.**

Defendants Wockhardt Limited and Wockhardt USA, Inc. (collectively “Wockhardt”) hereby answer the Complaint for Patent Infringement of Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively “sanofi-aventis U.S.”) as follows:

Parties

1. Wockhardt is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 1 of the Plaintiffs’ Complaint and, therefore, denies them.

2. Wockhardt is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 of the Plaintiffs' Complaint and, therefore, denies them.

3. Defendant Wockhardt USA, Inc. admits that it is a wholly-owned subsidiary of Wockhardt EU Operations (Swiss) AG, which in turn, is a wholly-owned subsidiary of Wockhardt Limited, having a principal place of business at 135 Route 202/206, Bedminster, New Jersey, 07921. Wockhardt denies all remaining allegations of Paragraph 3 of the Plaintiffs' Complaint.

4. Defendant Wockhardt Limited admits that it is an Indian corporation having a principal place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Wockhardt Limited admits that it manufactures generic drugs for sale and use throughout the United States, including this judicial district, through Wockhardt USA, Inc., a wholly-owned subsidiary of Wockhardt EU Operations (Swiss) AG.

Nature of the Action

5. Wockhardt admits that the Complaint purports to state a cause of action under the United States patent laws, 35 U.S.C. §1 *et seq* for infringement of United States Patent No. 6,149,940 ("the '940 patent"). Wockhardt denies the remaining allegations contained in Paragraph 5 of the Plaintiffs' Complaint.

Jurisdiction and Venue

6. Paragraph 6 of the Complaint states a legal conclusion as to which no response is required. To the extent a response is required, Wockhardt admits that this Court has jurisdiction over the subject matter of this action.

7. Paragraph 7 of the Complaint states a legal conclusion as to which no response is required. To the extent a response is required, Wockhardt admits that this Court has personal jurisdiction over defendant Wockhardt USA, Inc., because it is a Delaware Corporation; Wockhardt further admits that this Court has personal jurisdiction over defendant Wockhardt Limited by consent, and solely for purposes of this action. Wockhardt denies the remaining allegations of Paragraph 7 of the Plaintiffs' Complaint.

8. Paragraph 8 of the Complaint states a legal conclusion as to which no response is required. To the extent a response is required, Wockhardt admits that this Court has personal jurisdiction over Defendant Wockhardt USA, Inc.

9. Paragraph 9 of the Complaint states a legal conclusion as to which no response is required. To the extent a response is required, Wockhardt Limited admits that this Court has personal jurisdiction over it by consent, and solely for purposes of this action, but denies the remaining allegations of Paragraph 9 of the Plaintiffs' Complaint.

10. Paragraph 10 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Wockhardt admits that venue is proper in this judicial district for this action only.

The '940 Patent

11. Wockhardt admits that the '940 patent is entitled "Tablet with Controlled Release Alfuzosine Chlorhydrate," bears an issue date from the United States Patent and Trademark Office ("PTO") of November 21, 2000, and lists Jagotec AG as an assignee of the '940 patent, but denies that the '940 patent was duly issued by the PTO. Wockhardt also admits that the '940 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for Uroxatral® Oral Extended

Release Tablets (10 mg). Wockhardt is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 11 of the Plaintiffs' Complaint and, therefore, denies the same.

Acts Giving Rise to this Action
Infringement of the '940 Patent by Defendants

12. Wockhardt admits the allegations of the first two sentences of Paragraph 12, except that it denies that Wockhardt USA, Inc. submitted the ANDA on its own or as an agent of Wockhardt Limited, and denies that Wockhardt USA, Inc. is a subsidiary of Wockhardt Limited as explained above. Wockhardt Limited submitted the ANDA. As to the third sentence of Paragraph 12, Wockhardt Limited admits that it filed ANDA 90-221 seeking FDA approval for the generic product described therein prior to expiration of the '940 patent, but otherwise denies the allegations of that sentence.

13. Wockhardt admits that its ANDA contained a certification pursuant to 21 U.S.C. §355(j)(2)A)(vii)(IV) that to the best of its knowledge, no valid claim of the '940 patent would be infringed by the commercial manufacture, use, or sale of Wockhardt's ANDA Product in the United States. Wockhardt also admits that Wockhardt Limited provided Plaintiffs written notification of ANDA No. 90-221 on February 20, 2008. Wockhardt is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 13 of the Plaintiffs' Complaint and, therefore, denies the same.

14. Denied.

15. Denied.

16. Denied.

17. Wockhardt admits that it was aware of the existence of the '940 patent at the time of submission of ANDA No. 90-221. Wockhardt denies the remaining allegations of Paragraph 17 of the Plaintiffs' Complaint.

18. Denied.

Prayer for Relief

Wockhardt denies that Plaintiffs are entitled to any aspect of the judgment they seek.

DEFENSES

Wockhardt asserts the following defenses, reserving the right to supplement or amend these defenses as discovery proceeds.

FIRST DEFENSE
(Non-infringement of '940 Patent)

19. Wockhardt does not infringe, has not infringed, and does not and has not induced infringement or contributed to infringement of any valid claim of the '940 patent, either literally or under the doctrine of equivalents.

20. Wockhardt has not manufactured, used, sold, or offered for sale in the United States, or imported into the United States, any products that infringe any valid claim of the '940 patent, either literally or under the doctrine of equivalents and Wockhardt does not and has not induced infringement or contributed infringement of any valid claim of the '940 patent.

21. Wockhardt's ANDA product would not infringe any valid claim of the '940 patent, either literally or under the doctrine of equivalents, if manufactured, used, sold, or offered for sale in the United States, or imported into the United States and Wockhardt would not induce infringement or contribute to infringement of any valid claim of the '940 patent if it were to manufacture, use, sell, or offer for sale in the United States or import into the United States, its ANDA product.

SECOND DEFENSE
(Estoppel/Disclaimer of Claim Scope)

22. Plaintiffs are estopped from asserting any scope for one or more of the claims of the '940 patent which would cover Wockhardt's ANDA Product because of amendments, representations, assertions, disclaimers and/or admissions made during the course of proceedings in the United States Patent and Trademark Office ("PTO") during prosecution of the application leading to the issuance of the '940 patent ("the '940 patent application"), including but not limited to, prosecution disclaimer.

THIRD DEFENSE
(Estoppel)

23. To the extent not encompassed by Wockhardt's Second Defense, Plaintiffs are estopped from construing the claims of the '940 patent to cover and include Wockhardt's ANDA Product.

FOURTH DEFENSE
(Invalidity)

24. The '940 patent is invalid for failure to satisfy the provisions of one or more sections of Title 35 of the United States Code, and/or for failure to satisfy judicially-created requirements for patentability and enforceability of patents.

WOCKHARDT'S COUNTERCLAIMS

Defendants/Counterclaimants Wockhardt Limited and Wockhardt USA, Inc. (collectively "Wockhardt") hereby allege the following counterclaims against Plaintiffs/Counterdefendants sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis U.S."), for declaratory judgment that U.S. Patent No. 6,149,940 is invalid, unenforceable and/or not infringed by the alfuzosin hydrochloride extended release tablets (10 mg) ("Wockhardt's ANDA Product") described in Wockhardt's Abbreviated New Drug Application ("ANDA") No. 90-221 and associated drug master file(s).

PARTIES, JURISDICTION AND VENUE

25. Defendant and Counterclaimant Wockhardt Limited is a corporation organized and existing under the laws of India, having a principal place of business at Wockhardt Tower, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Defendant and Counterclaimant Wockhardt USA, Inc. is a wholly-owned subsidiary of Wockhardt EU Operations (Swiss) AG, which, in turn, is a wholly-owned subsidiary of Wockhardt Limited. Wockhardt USA, Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 135 Route 202/206, Bedminster, New Jersey, 07921.

26. On information and belief, sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

27. On information and belief, sanofi-aventis U.S. LLC is a limited liability company organized and existing under the laws of Delaware with its North American Headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

28. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367(a), 2201 and 2202, and 35 U.S.C. § 1, *et seq.*

29. Each of sanofi-aventis U.S. LLC and sanofi-aventis has submitted to the personal jurisdiction of this Court by virtue of by sanofi-aventis and sanofi-aventis U.S. LLC having filed suit against Wockhardt.

30. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400 and because this suit was filed in this judicial district by sanofi-aventis and sanofi-aventis U.S. LLC.

THE CONTROVERSY

31. This is an action based on an actual controversy between Wockhardt and sanofi-aventis U.S. concerning the non-infringement and/or invalidity of the '940 patent, and Wockhardt's right to continue to seek approval of Wockhardt's ANDA Product, and upon approval by the FDA, to manufacture, use, sell and offer to sell and import into the United States its proposed ANDA product.

32. United States Patent No. 6,149,940 is entitled "Tablet With Controlled Release of Alfuzosine Chlorohydrate," bears an issue date from the United States Patent and Trademark Office ("PTO") of November 21, 2000, lists Synthelabo and Jagotec AB as assignees, and lists as inventors Lauretta Maggi, Ubaldo Conte, Pascal Grenier, Guy Vergnault, Alain Dufour, Xavier Jarreau and Clemence Rauch-Desanti.

33. Sanofi-aventis U.S. has alleged that one or more claims of the '940 patent would be infringed by Wockhardt's proposed alfuzosin hydrochloride extended release tablets (10 mg), and that the filing of Wockhardt's ANDA constitutes infringement of the '940 patent. Sanofi-aventis U.S. has represented that it currently markets and sells a tablet product containing 10 mg of alfuzosin hydrochloride per tablet under the brand name Uroxatral®.

34. Wockhardt Limited has submitted, and is continuing to seek FDA approval of ANDA No. 90-221, directed to a product containing 10 mg alfuzosin hydrochloride per tablet, and approval to engage in the commercial manufacture, use, offer for sale, sale, and importation into the United States.

35. By letter of February 20, 2008, Wockhardt informed sanofi-aventis U.S. that it had submitted to the FDA, ANDA No. 90-221 directed to a proposed alfuzosin hydrochloride extended release tablet (10 mg) product, offered sanofi-aventis U.S. confidential access to the ANDA, and stated that the manufacture, use, offer for sale or sale of its proposed tablet product would not infringe any valid claim of the '940 patent.

36. Wockhardt has undertaken substantial efforts in developing and seeking approval for the alfuzosin hydrochloride extended release tablet (10 mg) product set forth in its ANDA.

37. Sanofi-aventis U.S. has alleged that Wockhardt Limited's submission of ANDA 90-221 to the FDA constitutes infringement of the '940 patent, and that Wockhardt's commercial manufacture, use, offer for sale or sale of its proposed generic product would infringe the '940 patent.

38. In view of the foregoing, an actual justiciable controversy exists by virtue of Wockhardt's notification to sanofi-aventis U.S. of its ANDA filing and sanofi-aventis U.S.' subsequent filing of the present suit as to Wockhardt's right to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and importation into the United States, the alfuzosin hydrochloride tablet (10 mg) product described in its ANDA.

COUNTERCLAIM I
(Non-infringement of the '940 Patent)

39. Wockhardt repeats and realleges paragraphs 1-38 above as if fully set forth herein.

40. Wockhardt does not infringe, has not infringed, and does not and has not induced infringement or contributed to infringement of any valid claim of the '940 patent, either literally or under the doctrine of equivalents.

41. Wockhardt has not manufactured, used, sold, or offered for sale in the United States, or imported into the United States, any products that infringe any valid claim of the '940 patent, either literally or under the doctrine of equivalents and Wockhardt does not and has not induced infringement or contributed infringement of any valid claim of the '940 patent.

42. Wockhardt's ANDA product would not infringe any valid claim of the '940 patent, either literally or under the doctrine of equivalents, if manufactured, used,

sold, or offered for sale in the United States or imported into the United States and Wockhardt would not induce infringement or contribute to infringement of any valid claim of the '940 patent if it were to manufacture, use, sell, or offer for sale in the United States, or import into the United States, its ANDA product.

43. Sanofi-aventis is estopped from asserting any scope for one or more of the claims of the '940 patent which would cover Wockhardt's proposed alfuzosin hydrochloride extended release tablet (10 mg) because of amendments, representations, assertions, disclaimers and/or admissions made during the course of proceedings in the PTO during prosecution of the application leading to the issuance of the '940 patent and other sanofi-aventis U.S. patents/applications and foreign counterparts of any such applications or patents, including but not limited to, prosecution disclaimer.

COUNTERCLAIM II
(Invalidity of the '940 Patent)

44. Wockhardt repeats and realleges paragraphs 1-43 above as if fully set forth herein.

45. Each and every claim of the '940 patent is invalid for failure to meet the statutory requirements of one or more sections of Title 35 of the United States Code, and/or for failure to satisfy judicially-created requirements for patentability and enforceability of patents.

DEMAND FOR JUDGMENT

WHEREFORE, Wockhardt prays for the following relief:

- (1) That any and all relief requested by sanofi-aventis U.S., as set forth in the Prayer of Relief of the Complaint, be denied and that the Complaint be dismissed with prejudice;
- (2) That a judgment be entered declaring that Wockhardt has not and does not infringe any claim of United States Patent No. 6,149,940;

- (3) That a judgment be entered declaring all claims of United States Patent No. 6,149,940 invalid;
- (4) That Wockhardt has a lawful right to seek and obtain FDA approval of its ANDA for its alfuzosin hydrochloride extended release tablet (10 mg) product, and that based on the non-infringement and invalidity of United States Patent No. 6,149,940, Wockhardt has a right to import, manufacture, use, offer for sale and sell its proposed alfuzosin hydrochloride extended release tablet (10 mg) product once approved by FDA;
- (5) That sanofi-aventis U.S., its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them, be preliminarily and permanently enjoined from threatening or initiating further infringement litigation against Wockhardt or any of its customers, dealers or suppliers, or any prospective sellers, dealers, distributors or customers of Wockhardt, or charging any of them either orally or in writing with infringement of United States Patent No. 6,149,940;
- (6) That a judgment be entered declaring this case to be exceptional within the meaning of 35 U.S.C. §285 and that Wockhardt is entitled to recover its reasonable attorneys' fees upon prevailing in this action;
- (7) That Wockhardt be awarded costs, attorneys' fees and other relief, both legal and equitable, to which they may be justly entitled; and
- (8) That Wockhardt be awarded such other relief as this Court deems just and proper.

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Dated: May 7, 2008

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I hereby certify that on May 7, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF which will send notification of such filing to the following and which has also been served as noted:

BY E-MAIL AND HAND DELIVERY

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I hereby certify that on May 7, 2008, the foregoing document was sent to the following non-registered participants in the manner indicated:

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